

(2) IT HAS AN ESTABLISHED NAME AND, TO THE EXCLUSION OF ANY OTHER NONPROPRIETARY NAME EXCEPT THE APPLICABLE SYSTEMATIC CHEMICAL NAME OR THE CHEMICAL FORMULA OF THE DRUG, ITS LABEL DOES NOT BEAR THE ESTABLISHED NAME OF THE DRUG;

(3) EXCEPT AS OTHERWISE PERMITTED BY A RULE OR REGULATION ADOPTED UNDER THE FEDERAL ACT OR BY THE SECRETARY UNDER SUBSECTION (D)(2) OF THIS SECTION, IT IS MADE FROM 2 OR MORE INGREDIENTS AND ITS LABEL DOES NOT BEAR THE ESTABLISHED NAME, IF ANY, OF AND THE QUANTITY OF EACH ACTIVE INGREDIENT, INCLUDING THE KIND AND QUANTITY OR PROPORTION OF ANY ALCOHOL AND, WHETHER ACTIVE OR NOT, THE ESTABLISHED NAME AND QUANTITY OR PROPORTION OF ANY BROMIDES, ETHER, CHLOROFORM, ACETANILID, ACETOPHENETIDIN, AMIDOPYRINE, ANTIPYRINE, ATROPINE, HYOSCINE, HYOSCYAMINE, ARSENIC, DIGITALIS, DIGITALIS GLUCOSIDES, MERCURY, OUABAIN, STROPHANTHIN, STRYCHNINE, THYROID, OR ANY DERIVATIVE OR PREPARATION OF ANY OF THESE SUBSTANCES, BUT A NONPRESCRIPTION DRUG IS NOT MISBRANDED UNDER THIS ITEM ON THE GROUND THAT ITS LABEL DOES NOT SHOW THE QUANTITY OR PROPORTION OF AN ACTIVE INGREDIENT UNLESS THE INGREDIENT IS SPECIFICALLY NAMED IN THIS ITEM;

(4) EXCEPT AS OTHERWISE PERMITTED BY A RULE OR REGULATION ADOPTED UNDER THE FEDERAL ACT OR BY THE SECRETARY UNDER SUBSECTION (D)(2) OF THIS SECTION, IT IS A PRESCRIPTION DRUG, AND THE ESTABLISHED NAME OF THE DRUG AND ANY OF ITS INGREDIENTS ARE NOT:

(I) PRINTED PROMINENTLY ON THE LABEL OF THE DRUG IN TYPE AT LEAST HALF AS LARGE AS THAT USED TO PRINT ANY PROPRIETARY NAME OR OTHER DESIGNATION OF THE DRUG OR OF ITS INGREDIENTS; AND

(II) PRINTED IN THIS SAME MANNER ON ANY LABELING OF THE DRUG ON WHICH ANY NAME FOR THE DRUG OR FOR AN INGREDIENT IS USED;

(5) IT PURPORTS TO BE A DRUG WHOSE NAME IS RECOGNIZED IN AN OFFICIAL COMPENDIUM AND IT IS NOT:

(I) LABELED AS REQUIRED BY THE APPLICABLE OFFICIAL COMPENDIUM; OR

(II) PACKAGED AS REQUIRED BY:

1. THE APPLICABLE OFFICIAL COMPENDIUM; OR

2. A CONSENT ORDER GRANTED UNDER THE FEDERAL ACT OR BY THE SECRETARY TO MODIFY THE PACKAGING REQUIREMENTS OF THE OFFICIAL COMPENDIUM;